

Therapeutic Area (Disease/Domain) Data Standards Prioritization

This document is a tabular representation of the data graphically shown in the Roadmap for Development of Priority Therapeutic Area (TA) Standards document. It has been developed so additional information can be easily added periodically to communicate information regarding TA development projects.

Number	TA	Roadmap Grouping ¹	Commenced (Y, Next Priority)	Start Date	Added to List ²	Removed from List ²	Tier ³	Stage ^{4,5}
1	Alzheimer's	1	Y				Tier 1	Public Release, v2.0 Provisional
2	Cardiovascular (CV)	1	Y				Tier 1	Public Release, v1.0 Provisional
3	CV Imaging (Echo)	1	Y		version 1			CFAST: Development
4	Pain	1	Y				Tier 1	Public Release, v1.0 Provisional
5	Parkinson's	1	Y				Tier 1	Public Release, v1.0 Provisional
6	Polycystic Kidney Disease	1	Y				Tier 1	Public Release, v1.0 Provisional
7	Schizophrenia	1	Y				Tier 1	Public Release, v1.0 Provisional
8	Tuberculosis	1	Y				Tier 1	Public Release, v1.0 Provisional
9	Virology	1	Y		version 1			Public Release, v2.0 Provisional
10	Diabetes (previously Anti-diabetic agents)	2	Y	Q3 FY13			Tier 1	Public Release, v1.0 Provisional
11	Irritable bowel syndrome (IBD): Crohn's disease & Ulcerative colitis	2	Y	Q3 FY14	version 4	version 1	Tier 1	FDA: Requirements Definition
12	Major Depressive Disorder	2	Y	Q4 FY12			Tier 2	CFAST: Development
13	Complicated Urinary Tract Infections (cUTI)	2	Y	Q2 FY14			Tier 1	FDA: Requirements Definition
14	Acne	3	Y	Q1 FY13			Tier 1	FDA: Requirements Definition
15	Prevention of Pregnancy	3	Y	Q3 FY14			Tier 1	FDA: Requirements Definition
16	Rheumatoid Arthritis (RA)	3	Y	Q1 FY14			Tier 1	FDA: Requirements Definition; CFAST: Development
17	Complicated Skin and Skin Structure Infections (ABSSSI) (formerly Infection of Skin and/or Subcutaneous Tissue)	4	Y	FY15			Tier 1	FDA: Requirements Definition; CFAST: Proposed
18	QT Studies	4	Y	Q4 FY13			Tier 1	Public Release, v1.0 Provisional
19	Solid Organ Transplantation - Kidney	4	Y	Q1 FY14			Tier 1	FDA: Requirements Definition; CFAST: Proposed

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20	Influenza	5	Y	Q1 FY14			Tier 2	Public Release, v1.0 Provisional
21	Treatment of Postmenopausal Osteoporosis	5	Y	Q2 FY14			Tier 1	FDA: Requirements Definition
22	Anticonvulsants	6	Y	Q2 FY14			Tier 2	FDA: Requirements Definition
23	Dyslipidemia (formerly Lipid-altering Drug Groups)	6	Y	Q1 FY13			Tier 2	Public Release, v1.0 Provisional
24	Oncology - Breast	6	Y	Q2 FY14	version 5			FDA: Requirements Definition; CFAST: Development
25	Asthma	7	Y	Q1 FY13			Tier 2	Public Release, v1.0 Provisional
26	Bipolar Disorder	7	Y	Q4 FY14			Tier 2	Duke University: Development; CFAST: Proposed
27	Clostridium Difficile associated Diarrhea (formerly Clostridium Difficile Colitis)	7	Y	FY15			Tier 2	FDA: Requirements Definition; CFAST: Proposed
28	Muscular Dystrophy	7	Y	Q4 FY14	version 5			FDA: Requirements Definition; CFAST: Proposed
29	Oncology - Prostate	8	Y	Q4 FY14	version 5			FDA: Requirements Definition; CFAST: Development
30	Chemotherapy-induced Nausea and Vomiting	8	Y	FY15			Tier 3	Research Triangle Institute: Requirements Definition
31	COPD	8	Y	Q4 FY14			Tier 3	Public Release, v1.0 Provisional
32	Complicated Intra-Abdominal Infections (formerly Infectious Diseases of Abdomen)	8	Y	FY15			Tier 3	FDA: Requirements Definition
33	General Anxiety Disorder	9	Y	Q4 FY14			Tier 3	Duke University: Development; CFAST: Proposed
34	Treatment of Hepatitis C	9	Y	Q2 FY13			Tier 1	Public Release, v1.0 Provisional
35	Diabetic Nephropathy (also called Diabetic Kidney Disease)	9	Y	Q3 FY14			Tier 2	FDA: Requirements Definition; CFAST: Development
36	Attention Deficit Hyperactivity Disorder (ADHD)	9	Y	Q2 FY14			Tier 3	FDA: Requirements Definition
37	Treatment of Overactive Bladder	10	Y	Q1 FY13			Tier 2	FDA: Requirements Definition
38	Oncology - Colorectal	10	Y	FY15	version 5			FDA: Requirements Definition; CFAST: Development

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39	Oncology - Lung	10	Y	FY15	version 5			FDA: Requirements Definition; CFAST: Proposed
40	Oncology - Brain	10	Y		version 7			FDA: Requirements Definition
41	Anticoagulants for Atrial Fibrillation (formerly Atrial Fibrillation)	11	Y	Q2 FY14			Tier 3	FDA: Requirements Definition
42	Traumatic Brain Injury	11	Y	Q4 FY14			Tier 3	Public Release, v1.0 Provisional
43	Psoriasis	12	Next Priority		version 6	version 4	Tier 1	CFAST: Proposed
44	Oncology – Cervical Cancer	12	Next Priority		version 8			
45	Decompensated Congestive Heart Failure (CHF)	12	Next Priority				Tier 3	
46	Acute Kidney Injury	12	Next Priority					
47	Opioid Induced Constipation	13		2017	version 1			
48	Treatment of Hepatitis B	13		2017			Tier 3	
49	Tinea Pedis	13	Next Priority				Tier 3	
50	Chronic Idiopathic Constipation	14		2017	version 1			
51	Treatment of HIV*	14					Tier 2	
52	Prevention of HIV*	14					Tier 2	
53	Treatment of Vasomotor Symptoms Due to Menopause	15	Next Priority				Tier 2	
54	Actinic Keratoses	15	Next Priority				Tier 3	
Removed from List								
	Sedation	15			version 1	version 8		
	Pneumonia	6				version 6	Tier 2	
	Treatment of Cough	9				version 6	Tier 3	
	Bacterial Vaginosis	9				version 6	Tier 3	
	Aerosolized Antimicrobials for Cystic Fibrosis	10				version 6	Tier 3	
	Helicobacter Pylori Ulcer Disease	13				version 6	Tier 3	
	Magnetic Resonance Imaging (MRI) Contrast Agent	6				version 6	Tier 3	

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	Diagnostic Radiopharmaceutical	4				version 6	Tier 3	
	Treatment of Erectile Dysfunction	12				version 6	Tier 3	
	Hyperdynamic Lines	10				version 6	Tier 3	
	Recombinant Human Growth Hormone Products	14				version 6	Tier 3	
	Oncology: Time to Efficacy Event - other than overall survival (e.g., progression-free survival, disease-free survival, etc.)	2				version 5	Tier 1	With the availability of the SDTM Oncology domain models for Tumor Identification (TU), Tumor Results (TR) and Disease Response (RS) in SDTMIG v3.1.3 and later and the revised approach to develop the Oncology TA by body system (e.g., Oncology - Breast) this TA is being removed from the list.
	Oncology: Objective Tumor Response (including Complete Response, Partial Response etc.)	3				version 5	Tier 2	See note for previous item.
	Gastroesophageal Reflux Disease	2				version 4	Tier 2	
	Addiction					version 1	Tier 2	

* Detailed requirements are already defined

¹ Roadmap Grouping reflects the grouping of each TA as shown on the Roadmap for Development of Priority Therapeutic Area Standards document.

² FDA updates the TA list periodically based on feedback from the CDER Review Divisions. The version of this document where a TA was added or removed is shown here for tracking purposes.

³ Tier shows the original tier information assigned in November 2011 for historical tracking purposes. This was replaced by the information in the Roadmap Grouping column.

⁴ For Stage term definitions see Table 6 of the CDER Data Standards Strategy Action Plan available on the CDER Data Standards Program webpage. To see current progress for those listed with "CFAST: Development" or to see the list of "CFAST: Proposed", go to www.cdisc.org/therapeutic

⁵ Acronyms: Clinical Data Interchange Standards Consortium (CDISC), Coalition for the Advancement of Standards and Therapies (CFAST), Critical Path. The term "therapeutic area" also includes diagnostic and preventive areas. Some areas may represent a disease/domain area.

Note: To see the CFAST TA plan, go to <http://www.cdisc.org/therapeutic>

Initial Version, November 2011

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					version 1, 09-28-2012			version 6, 07-17-2015
					version 2, 02-21-2013			version 7, 11-23-2015
					version 3, 07-22-2013			version 8, 04-08-2016
					version 4, 10-29-2013			version 9, 04-19-2016
					version 5, 09-09-2014			